7	CAS No.: 7440-45-1 (Cerium)	Substance: Cerium and its compounds

Chemical Substances Control Law Reference No.:

PRTR Law Cabinet Order No.:

Atomic symbol: Ce

Atomic Weight: 140.116

1. General information

Cerium compounds include cerium oxide, cerium carbonate, and cerium chloride. Cerium oxide and cerium carbonate are insoluble in water, while cerium chloride is soluble in water.

The main uses of cerium are glass abrasives, catalysts, UV-shielding glass, and glass achromatizing agents. The main uses of cerium oxide are sheet glass polishing, lens achromatizing, cathode ray tube (CRT) lapping, optical glass lapping, and as an automobile exhaust gas catalyst. Furthermore, cerium oxide is added to CRTs. The main uses of cerium chloride are mischmetals, rare earth compound raw materials, and raw materials for cerium compounds. The production (shipments) and import quantity in fiscal 2007 was 1,000 to <10,000t/y for both cerium oxide and cerium carbonate.

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2. Exposure assessment

Because this substance is not a Class 1 Designated Chemical Substance under the Law Concerning Reporting, etc. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management (PRTR Law), release and transfer quantities could not be obtained. Predicting distribution by medium was not considered appropriate because the chemical forms adopted by cerium and its compounds in the environment are not clearly understood. Accordingly, a prediction of distribution by medium for cerium and its compounds was not carried out.

The predicted maximum exposure to humans via inhalation, based on general environmental atmospheric data, was around 0.0078 μg/m^3. The predicted maximum oral exposure was estimated to be around 0.45 μg/kg/day based on based on calculations from data for soil.

The predicted environmental concentration (PEC), which indicates exposure to aquatic organisms, could not be set because water quality data could not be obtained.

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3. Initial assessment of health risk

Cerium compounds used to be widely used as anticoagulant agents, but their intravenous infusions caused algor, pyrexia, headache, myalgia, abdominal twitch and hemoglobinuria as side-effects. Workers who handled cerium and its compounds, however, have not indicated disorders with such symptoms.

Sufficient information could not be obtained on its carcinogenicity, and its initial assessment was conducted on the basis of data on its non-carcinogenic effects.

As for its oral exposure, its NOAEL of 60 mg/kg/day (for suppressed body weight increase) obtained from mid-term and long-term toxicity tests for rats with mixture of rare earth elements in nitrate was converted to 21 mg/kg/day for cerium as its 'non-toxic level*'. As for its inhalation exposure, its LOAEL of 5 mg/m^3 (for hyperplasia of lymph tissue in bronchial lymph nodes) was obtained from mid-term and long-term toxicity tests for rats inhaled with cerium oxides. This was adjusted against exposure conditions to produce 0.89 mg/m^3, which was then divided by 10 as is always the case with LOAEL. This was divided by 10 again, due to their short test periods, to provide 0.0089 mg/m^3. Finally, this was converted to 0.0072 mg/m^3 for cerium as its 'non-toxic level*'.

As for oral exposure, the maximum exposure for cerium was estimated to be around 0.45 μg/kg/day, when intakes of soil were assumed. Its margin of exposure (MOE) would be 4,700, when calculated from its 'non-toxic level*' of 21 mg/kg/day and its estimated maximum exposure, and then divided by 10 due to the fact that the 'non-toxic level*' was obtained from animal experiments. No further action will be required at the moment to assess health risk from oral

exposure to this substance through soil. However, its exposure through drinking water is yet to be understood, and collection of information on its oral exposure is required.

As for inhalation exposure, the maximum exposure concentration for cerium was estimated to be around 0.0078 μg/m^3, when its concentrations in the ambient air were considered. Its MOE would be 92, when calculated from its 'non-toxic level*' of 0.0072 mg/m^3 and its estimated maximum exposure concentration, and then divided by 10 due to the fact that 'non-toxic level*' was obtained from animal experiments. Collection of information would be required to assess health risk from inhalation exposure to this substance in the ambient air.

As for nanomaterial made of cerium oxides, their particles are so small that their metabolism, dynamics and toxicology would be different. Based on the information on exposure to them, separate risk assessment should to be considered for them.

Information of toxicity				Exposure assessment		Result of risk assessment			Judgment
Exposure Path	Criteria for risk assessment	Animal	Criteria for diagnoses (endpoint)	Exposure medium	Predicted maximum exposure quantity and concentration				
Oral	'Non-toxic level*' 21 mg/kg/day	Rats	suppressed body weight increase	Drinking water	— μg/kg/day	MOE	—	×	(▲)
				Soil	0.45 μg/kg/day	MOE	4,700	○	
Inhalation	'Non-toxic level*' 0.0072 mg/m^3	Rats	hyperplasia of lymph tissue in bronchial lymph nodes	Ambient air	0.0078 μg/m^3	MOE	92	▲	▲
				Indoor air	— μg/m^3	MOE	—	×	×

Non-toxic level *

- When a LOAEL is available, it is divided by 10 to obtain a level equivalent to NOAEL.
- When an adverse effect level for the short-term exposure is available, it is divided by 10 to obtain a level equivalent to an adverse effect level for the long-term exposure.

Note: Estimated maximum exposure (concentration) and 'non-toxic level' are presented as those for cerium.

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4. Initial assessment of ecological risk

Suficient appropriate data regarding the toxicity of this substance towards aquatic organisms and its concentration in water could not be obtained. Accordingly, such data will be compiled in the future.

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5. Conclusions

	Conclusions		Judgment
Health risk	Oral exposure	Oral exposure through drinking water is yet to be understood, and collection of information on this oral exposure is required.	(▲)
	Inhalation exposure	Collection of information required on health risk associated with inhalation exposure in the ambient air.	▲
Ecological risk	Sufficient appropriate data regarding the toxicity of this substance towards aquatic organisms and its concentration in water could not be obtained. Accordingly, such data will be compiled in the future.		(—)

[Risk judgments] ○: No need for further work ▲: Requiring information collection
■: Candidates for further work ×: Impossibility of risk characterization
(○) : Though a risk characterization cannot be determined, there would be little necessity of collecting information.
(▲) : Further information collection would be required for risk characterization.